

REMARKS

Reconsideration of the present application in view of the above amendments and following remarks is requested respectfully.

Claims 1 to 47 are pending in the present application. Claims 4 and 17 have been amended.

The Office Action includes rejections under 35 U.S.C. § 112, first and second paragraphs, which are addressed below.

Discussion of the Rejections Under Section 112, Second Paragraph

Claims 1 to 47 stand rejected under 35 U.S.C. § 112, second paragraph, for allegedly failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. Applicants traverse respectfully this rejection and submit that one of skill in the art having read the present specification and claims would appreciate the metes and bounds of the claimed inventions.

As set forth in MPEP §2173.02, the “essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity.” “If the scope of the subject matter embraced by the claims is clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. §112, second paragraph.” MPEP §2173.04.

The Office Action asserts that claims 1 to 47 are indefinite because the group defined as “C<sub>3</sub>-C<sub>9</sub> heteroaryl” is allegedly indefinite because a “heteroaryl necessarily requires the presence

of a heteroatom and cannot be made of only carbon atoms” (Office Action at 2). The group defined as “C<sub>3</sub>-C<sub>9</sub> heteroaryl,” however, would be clear to those skilled in the art in the context of Applicants’ specification. Significantly, the group “C<sub>3</sub>-C<sub>9</sub> heteroaryl,” is expressly defined in Applicants’ specification to include the presence of “from 1 to 3 nitrogen, oxygen, and sulphur atoms” (page 9, lines 23 to 26). Thus, when the instant claims are read in light of the specification as they should be, one skilled in the art would indeed understand the scope of the group “C<sub>3</sub>-C<sub>9</sub> heteroaryl” to include at least one heteroatom. *In re Cohn*, 169 USPQ 95 (C.C.P.A. 1971) (the claims must be read in light of the specification). Accordingly, Applicants submit respectfully that the rejection under 35 U.S.C. § 112, second paragraph, should be reconsidered and withdrawn.

#### Discussion of the Rejections Under Section 112, First Paragraph

Claims 36, 37, 41, 42, and 46 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly not being enabled with regard to treating the diseases embraced by the claims. Applicants traverse respectfully this rejection and request reconsideration because the Office Action has not met its burden to establish a reasonable basis to question the enablement provided for the claimed invention.

It is settled law that whenever the adequacy of enablement provided by an applicant’s specification is challenged, the examiner has the initial burden of giving reasons, supported by the record as a whole, why the specification is not enabling. *In re Armbruster*, 185 U.S.P.Q. 152 (C.C.P.A. 1975). The enablement requirement of 35 U.S.C. §112 is satisfied if a disclosure contains sufficient information such that persons of skill in the art, having the disclosure before

them, would be able to make and use the invention. The legal standard for enablement under §112 is whether one skilled in the art would be able to practice the invention without undue experimentation. *In re Wands*, 8 U.S.P.Q. 1400 (Fed. Cir. 1988). Any experimentation that may be required is not undue as long as it is of a routine nature. *Ex parte Forman*, 230 U.S.P.Q. 546, 547 (Pat. Off. Bd. App. 1986). As the Federal Circuit noted:

The test [for undue experimentation] is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable to determination of how to practice a desired embodiment of the claimed invention.

*PPG Indus., Inc. v. Guardian Indus. Corp*, 37 U.S.P.Q.2d 1618, 1623 (Fed. Cir. 1996) (quotation and citation omitted).

In the first instance, Applicants' disclosure indeed contains sufficient information to allow persons skilled in the art to practice the claimed methods of treating diseases that are characteristic of over-expression and activation of matrix metalloproteinase such as, for example, cardiovascular disease and multiple sclerosis. For example, pages 134 to 138 of Applicants' specification detail the methods of the claimed invention and pages 141 to 142 detail the *in vivo* practice of such methods. Such disclosure includes, for example, literature references to techniques that are well-known in the art and is indeed supportive of enablement of the claimed method of inhibiting matrix metalloproteinase in a patient in need thereof. Accordingly, any experimentation that may be required would not be undue in view of said teachings. *Ex parte Forman*, 230 U.S.P.Q. 546, 547 (Pat. Off. Bd. App. 1986).

Moreover, the Office Action has failed to satisfy its burden to provide evidence of a reason to doubt that those skilled in the art would be unable to practice Applicants' claimed

invention. With regard to the enablement determination, the following statement from *In re Marzocchi*, 169 U.S.P.Q. 367, 369-70 (C.C.P.A. 1971), is noteworthy:

The only relevant concern of the Patent Office under these circumstances should be over the truth of any assertion. The first paragraph of §112 requires nothing more than objective enablement. How such a teaching is set forth, either by use of illustrative examples or by broad terminology, is of no importance.

As a matter of Patent Office practice, then, a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirements of the first paragraph of §112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied upon for enabling support.

The law thus requires that the Patent Office accepts Applicants' assertions of enablement or provide reasoning and evidence to substantiate doubts of the objective truth of Applicants' assertions. *In re Dinh-Nguyen*, 181 U.S.P.Q. 46 (C.C.P.A. 1974); *In re Bowen*, 181 U.S.P.Q. 48 (C.C.P.A. 1974).

The Office Action, however, has provided no factual evidence indicating a reason to doubt that Applicants' disclosure would enable those skilled in the art to practice the claimed methods. The Office Action, for example, expresses doubt that the claimed compounds could be used to treat the diseases embraced by the claims (Office Action at 2-3), but provides *no evidence* as to how and why the teachings in Applicants' specification are not true such that the method claims would not be enabled. Rather, the only support offered by the Office Action are mere bare assertions that, for example, "one skilled in the art cannot say for sure which patient is in need of inhibition of MMP" (Id. at 3), and "the skilled clinician would not know how to use [MMP inhibitors] to treat MS with Applicants' compounds" (Id. at 4). In this regard, the Office

Action has provided *no factual evidence or technical reasoning* to support the bare assertions contained therein. Accordingly, the Office Action has failed to satisfy its burden to provide evidence of a reason to doubt that those skilled in the art would be unable to practice Applicants' claimed invention. Absent some reason to doubt the truth of statements made in Applicants' disclosure regarding enablement, practice of the pending claims must be deemed enabled. *In re Wright*, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993). Accordingly, Applicants respectfully request that the rejection for alleged lack of enablement be reconsidered and withdrawn.

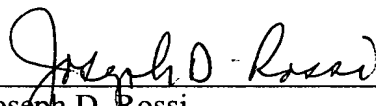
Conclusion

Applicants believe that the foregoing constitutes a complete and full response to the Office Action of record. Accordingly, an early and favorable reconsideration of the rejections and an early and favorable allowance of all of pending claims are requested respectfully.

In the event any issues remain outstanding, the Examiner is requested to call the undersigned at the telephone number listed below.

The Commissioner is authorized hereby to charge any fees or credit any overpayment associated with this Reply (copy enclosed) to Deposit Account Number 19-5425.

Respectfully submitted,  
Synnestvedt & Lechner LLP

  
\_\_\_\_\_  
Joseph D. Rossi  
Registration No. 47,038

Synnestvedt & Lechner LLP  
2600 Aramark Tower  
1101 Market Street  
Philadelphia, PA 19107  
Telephone (215) 923-4466  
Facsimile (215) 923-2189  
Email [jrossi@synnlech.com](mailto:jrossi@synnlech.com)